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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/796,834 | 03/09/2004 | Svein Brekke | 130394UL | 2461 |

7590 05/25/2006

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EXAMINER

JAWORSKI, FRANCIS J

ART UNIT PAPER NUMBER

3768

DATE MAILED: 05/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | | |
|------------------------------|------------------------|--|---------------------|--|
| Office Action Summary | Application No. | | Applicant(s) | |
| | 10/796,834 | | BREKKE ET AL | |
| | Examiner | | Art Unit | |
| | Jaworski Francis J. | | 3768 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 3/9/04 IDS.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 - 55 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 - 55 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>3/9/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1 – 20 and 30 – 38 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

The Patent Office current position is that for an apparatus or method claim to pass statutory muster under 35 USC 101, it must inter alia result in a physical transformation or produce a 'useful, concrete and tangible result'. Since the invention resides in the signal processing area it is the latter criteria that must be met. In the case of claim 1 which is directed to applicants' (subcombination) event trigger extraction system for example, the result is an abstraction in the sense that the claimed subject matter only results in the abstraction of a stored signal and does not provide a real world concrete and tangible result such as control of an image display. Since dependent claims 2 – 11 merely refine further signal processing instructions or the region from which the stored signal has been derived they group with the base claim.

Claim 12 and its dependencies while reciting the event trigger subsystem functionalities in terms of instructions stored in a memory so as to cause an imaging system to invoke the instructions nevertheless groups under the same rejection, namely that the instructions do not advance to a useful, concrete and tangible result.

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Claims 30 - 38 broadly track analogous claimed within the aforementioned apparatus subsystem in their method form and therefore are grouped for rejection for the same reason that a useful, concrete and tangible result is lacking.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1 – 2, 7, 12 – 13, 17, 19 – 21, 23-25, 28-30, 35, 37 – 39, 41 - 44 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 10, 20 of U.S. Patent No. 6652462. Although the conflicting claims are not identical, they are not patentably distinct from each other because the patent claims the apparatus for and method of determining a colorized imaging display time period based upon the algorithm automatically determining the interval (plural trigger-start and stop

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time extremes) boundaries by using as input motion parameter(s) derived from the ultrasound image whereupon it would have been inherently obvious to implement the claimed algorithm in conjunction with an implementing processor and memory for the algorithm to reside.

Claims 10 – 11, 26 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 10, 20 of U.S. Patent No. 6652462 in view of claims 4 and 6 of US6980844. Whereas the former does not claim fetal heart application and during volumetric scanning, it would have been obvious in view of the claim 6 subject matter of the latter to image a fetal heart and derive movement parameters therefrom since the base claim in the latter is similarly directed to determining a time interval for the periodic (heart) movement.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 – 2, 4, 6 - 8, 10 –13, 16 - 17, 19 – 30, 32, 34 – 35, 37 – 48, 50 – 52 and 55 are rejected under 35 U.S.C. 102(b) as being anticipated by Brekke et al (2002 IEEEUTS SYMP PROC> pp. 1593-96, of record with the 3/9/04 IDS filing).

Brekke et al teaches, prior to applicants' critical date, a trigger extraction apparatus and method and stored algorithm for operating a subsystem for a 3D

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ultrasound imaging system and 2D or 1.5D probe which system uses in-phase and quadrature phase tissue Doppler data from looped recording playback and derived from elevational beamformer defocusing about the B-scan tissue image plane for fixed 4-chamber fetal heart tissue view in an algorithm in which the autocorrelation lag 1 average or mean value of Doppler amplitude across the heart image is computed and minima extracted with option of use of positive extremum value alternative, and/or interpolative additional trigger computations per Fig. 2 to provide plural such triggers as well as delayed triggers per Fig. 3, which event triggers are stored for slow-speed comparison playbacks. Since implementation of such an algorithm defined in $R1$, r , θ and t and across all points of an image for 1,950 such stored image frames would be impossible without storage of the algorithm and association with a processor during its running which is also the case for application of EchoPAC3D view reconstruction software for the general imaging system which acts in cooperation with the algorithm software as described for synchronous viewing of the triggering curve and the synchronized rendered images, the listed claims are therefore met.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1 – 2, 4, 6 – 8, 10 – 13, 16 – 17, 19 – 30, 32, 34 – 35, 37 – 48, 50 – 52 and 55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brekke et al in view of Omiya (US6849048), alone or further In view of Jackson (US6673017). If the former be considered to be lacking with respect to feature extraction and transfer into storage, it would have been obvious in view of Omiya to provide software resident on a CD-ROM in 104 to implement by interfacing within processor 100 with display formatting software 102 to provide synchronization 106 for display by using a characteristic waveform such as LVV derived from an overlapping (ventricular wall subregion) of the cardiac image. Alternatively, if Omiya be viewed as revealing of the literal stored software and processor-software interactions to synchronize a tomographic image but itself be deficient regarding a Doppler basis for the characterizing waveform, then it would have been nonetheless been obvious to to use e.g. mean doppler velocity based upon autocorrelation determinations to provide a characterizing temporal wavetrace upon which to perform image registry.

[Alternately re-stated the Examiner's position is that, to the extent that Brekke et al lacks complete fleshing out of the processor-software interaction and storage of feature event extraction processes, one skilled in the art and also having before him Omiya directed to the registration of tomographic cardiac images and Doppler images (not Doppler based triggers) where ECG or other external synchronism is not suitable or available and teaching the alternative of an image-derived characterizing temporal reference and Jackson et al directed to registration of single B-modality ultrasound heart images but across plural heart cycles for high fidelity strain rate imaging or valve

motion study and teaching that for image-derived temporal waveform purposes a B-mode index (as defined col. 5 lines 26 – 30) is likenable to a Doppler image –derived index (as defined col. 6 lines 22 – 51) , that artisan would understand to flesh out Brekke et al with the latter patent teachings.]

Claims 3, 5, 9, 14-15, 18, 31, 33, 36 and 53 - 54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brekke et al alone or further in view of Omiya alone or with Jackson in supplement as applied to claims 1, 4, 8, 12, 30 above, and further in view of (a) Inuma et al (US5785654) or (b) Yamazaki et al (US5513640), or (c) Moehring et al (US2005/0033174). Whereas the Brekke et al article does not address high-pass filtering, it would none the less have been obvious in view of Inuma et al col. 7 lines 7 – 38 to set a high pass filter on phase-detected Doppler data since if one wishes to track valve motion or bloodflow then lower frequency tissue motion must be filtered, or it would have been obvious in view of Inuma et al col. 4 lines 32 – 62 to eliminate very low velocity movement since fixed locational change i.e. aggregate macro movement of the heart should be filter eliminated to derive net valve motion, or it would have been obvious in view of Moehring et al para [0037] to set a high-pass filter in application-specific fashion so as to eliminate bruits for example from Doppler flow data.

[Alternately stated, the Examiner is interpreting applicants' para [0028] to mean that the data set on which trigger extraction may be practiced can be either Doppler

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tissue velocity/TVI or bloodflow data (as might be advantageous in a contrast agent application for example) or para [0032] lines 5 – 10 might mean that the digital regression filter is set in a data dependent fashion (for example a maternal bruit might be confounding), and so multiple prior art items are applied, the net being that it would not appear that the high pass feature creates patentable distinction over Brekke et al.]

Claim 49 is rejected under 35 U.S.C. 103(a) as being unpatentable over Brekke et al alone or further in view of Omiya alone or further in view of Jackson as applied to claim 48 above, and further in view of Entrekin (US4503861) since whereas the former is silent as to azimuthal beam divergence, it would have been obvious in view of the latter to provide divergent de-focussing in all forward directions in order to increase the acceptance angle for the Doppler data since the exact location of the small fetal heart within the mother can't be precisely known

Claims 1 – 5, 12 – 15, 21, 25, 28 - 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Resnick et al (US6174287). Resnick et al is directed to the parallel display alongside the B-mode image of a continuous wave spectral Doppler strip image (col. 1 lines 52 – 58) or of a Doppler frequency shift/variance/amplitude/power or energy produced by phase detection and wall filtering and averaging(a high pass process), see col. 5 line 11 – col. 6 line 27. Hence while the purpose of Resnick et al is divergent from applicants', that is Resnick et al is concerned with using a Doppler signal which intersects the imaged ventricle to identify the time epoch milestones of contrast agent infusion such as perfusion measurement by virtue of

enhanced bloodflow energy returned after agent bright-up (col. 3 lines 38 – 44 and , and the direct time triggering is non-ultrasound in nature (using conventional ECG or user-triggering or clock time, see cols. 7 – 8), yet the M-mode line which may be Doppler-derived (col. 4 lines 35 – 37) serves as an event identifier for ECG triggering (cols. 3 – 4 bridging).

[Alternatively stated, since the event trigger is not claimed to exert a command or control such as gating, an event identifier based on an image motion parameter and provided as a wavetrace against which the user decides on an optimum ECG gate is argued to qualify as an 'event trigger'.]

Patentability Assessment

While patentable subject matter is not identified at this juncture, the rejection issues are restated in overview to assist applicants.

1) Claims 1 – 20 and 38 – 38 directed to apparatus subcombination/memory-resident instruction set and methodology for identifying an event trigger are considered to be non-statutory under 35USC101 whereas those directed to an imaging system with at least an instruction set for displaying an image (Claims 21 – 29) as well as those to the

method of image display (Claims 39 – 46) and the imaging system including the display which is acted upon by the event trigger instructions are all found to pass muster.

2) Some of the claims have been held to be rejectable on obviousness double patenting grounds since there is claimed subject matter overlap with GE Global Medical - assigned prior patents which claim inter alia a timing event control algorithm based on a set of ultrasound image parameter signals and which claim performing volume imaging of the fetal heart in synchronism with motion parameter timings.

3) Additionally the Brekke et al article 2002 IEEE UTS Symposium (10/2002) is at bar under 35 USC 102(b) against the majority of presented claims, and is combinable with prior art against all claims since high pass filtering and azimuthal defocusing features do not carry for patentability.


4) Since a 'pseudo-ECG' triggering system based on a 'characteristic waveform' and with proposal for software implementation based on CD-ROM storage was known by virtue of the Omiya patent whereby algorithm-based trigger extraction was based upon physiologic cyclicity of an ultrasound imaged portion, this patent serves as a basis for combination with Brekke et al if the latter be considered deficient for anticipatory purposes since the disclosure is narratively inferential of the means and steps and complete software for trigger event extraction and storage, when it is considered alone or in combination with Jackson et al as an ancillary prior art teachings as to how such an event trigger if including a Doppler-based trigger might be implemented

5) Since the event trigger extraction feature is not associated with direct command or control in any claim, nor does it exert a repetitive function, this leaves open the

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broadest reasonable interpretation that the claimed subsystem structure/stored instruction set and associated method embrace also the extraction of of a registration index waveform where a non-cyclic event (contrast agent injection bright-up of the ultrasound image) or a salient of the physiologic (M) wavetrace provide an index or reference including a Doppler-based reference for image triggering on other command bases, with claims applicability limited by the one-time event trigger nature of the reference and the lack of need for use of Doppler motion signal extrema (Resnick et al –based rejections).

Any inquiry concerning this communication should be directed to Jaworski Francis J. at telephone number 571-272-4738.



Francis J. Jaworski
Primary Examiner

FJJ:fjj

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